Billing code: 4150-28

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier OS-0990-0278]

Agency Information Collection Request. 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain . Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: Sherrette Funn, Sherrette.Funn@hhs.gov or (202) 795-7714. When submitting comments or requesting information, please include the document identifier 0990-0278 and project title for reference.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3)

ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Federal wide Assurance Form

Type of Collection: Extension

OMB No. 0990-0278- Office of the Assistant Secretary for Health, Office for Human Research Protections – Federal wide Assurance Form

Abstract: Assistant Secretary for Health, Office for Human Research Protections is requesting a three year extension of the Federal wide Assurance (FWA) form. The FWA is designed to provide a simplified procedure for institutions engaged in HHS-conducted or supported research to satisfy the assurance requirements of Section 491(a) of the Public Health Service Act and HHS Regulations for the protection of human subjects at 45 CFR 46.103.

Respondents are institutions engaged in human subject's research that is conducted or supported by HHS.

Estimated Annualized Burden Table

Type of Respondent	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Federal wide Assurance (FWA)	14,000	2.0	0.50	14,000
Total				14,000

Terry Clark, Office of the Secretary,

Asst Paperwork Reduction Act Reports Clearance Officer.

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